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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,126	06/06/2005	Shunsuke Kuroiwa	442P097	2218
42754	7590	10/12/2007		
NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581			EXAMINER JAISLE, CECILIA M	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 10/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/538,126	Applicant(s) KUROIWA ET AL.	
	Examiner Cecilia M. Jaisle	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 3-5 and 7-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :08-22-2005,, 03-08-2007 & 08-21-2007 .

## DETAILED ACTION

### *Lack of Unity*

**The following Lack of Unity requirement was made during a telephone conversation with Mr. Kevin S. Lemack in Jan. 2007 and Mr. Lemack provisionally elected with traverse to prosecute the invention of Group I:**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 2, 5, and 12- 14, drawn to compounds of Formulae (1) and (3) in which  $L = N-W$ , classified in class 540, subclasses 461 and 578 and class 544, subclass 236, and a cell proliferation inhibitor comprising them classified in class 514, subclass 248.
- II. Claims 1-4 and 12-14, drawn to compounds of Formulae (1) and (3) in which  $L = W-C-W'$ , classified in class 544, subclass 235, and a cell proliferation inhibitor comprising them classified in class 514, subclass 248.
- III. Claims 1, 6-8, and 12-14, drawn to compounds of Formulae (1) and (4) in which  $J-K-L-M = C(O-Y)=CH-C(W)=CH$ , classified in class 544, subclass 235, and a cell proliferation inhibitor comprising them classified in class 514, subclass 248.

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IV. Claims 1, and 12-14, drawn to compounds of Formula (2) in which L = N-W, classified in class 544, subclass 236, and a cell proliferation inhibitor comprising them classified in class 514, subclass 248.

V. Claims 1, and 9-14, drawn to compounds of Formula (2) in which L = W-C-W', classified in class 544, subclass 235, and a cell proliferation inhibitor comprising them classified in class 514, subclass 248.

Each group as set forth above lacks unity with each other group, i.e., there is no single general inventive concept. The unique special technical features in each group are the identities of the compounds of the two different Formulae (1) and (2), within the compounds of the Formula (1), the identity of the moiety L, and within the compounds of the Formula (2), the identity of the moiety L. The technical relationship among the inventions does not involve at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. In this case, a reference that could be used to reject the substituted 3-phenyl-pyrido-pyridazines of Group I could not be used to reject the substituted 3-phenyl-cycloalkyl-fused-pyridazines of Group II, the substituted 3-phenyl-benzo-pyridazines of Group III, the 3-phenyl-cycloalkyl-fused-partially-hydrogenated-pyridazines of Group IV, or 3-phenyl-partially-hydrogenated-pyrido-pyridazines of Group V.

The Group I invention has special technical features not common to Groups II-V and would be expected to be useful other than as disclosed, e.g., for their monoamine

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oxidase-A and -B inhibitory activity. Also, the Group II invention has special technical features not common to Groups I and III-V and would be expected to be useful other than as disclosed, e.g., as sedatives.

**Upon reconsideration by the Examiner, the original Lack of Unity requirement was seen to be unduly restrictive and the Lack of Unity requirement is revised as follows:**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1- 14, drawn to cinnoline compounds, classified in class 540, subclasses 461 and 578, and class 544, subclass 235 and 236, and a cell proliferation inhibitor comprising them, classified in class 514, subclass 248.

II. Claims 1-14, drawn to all other compounds of the Formulae (1) – (4), variously classified in classes 540 and 544, and a cell proliferation inhibitor comprising them, variously classified in class 514.

Each group as set forth above lacks unity with each other group, i.e., there is no single general inventive concept. The unique special technical features in each group

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are the identities of the compounds of the different Formulae (1) – (4), as to whether the compounds are cinnolines or other compounds within the Formulae. The technical relationship between the inventions does not involve at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. In this case, a reference that could be used to reject the substituted 3-phenyl-pyrido-pyridazines of Group I could not be used to reject the compounds of Group II.

The Group I invention has special technical features not common to Group II and would be expected to be useful other than as disclosed, e.g., for their monoamine oxidase-A and -B inhibitory activity (Thull, J. Med. Chem., 1998, 41, pages 3812-3820; cited by Applicants).

The election by Mr. Lemack noted above has been treated as an election with traverse of Group I, claims 1-14. Applicant must affirm this election in replying to this Office action. Claims 1-14 are under examination only to the extent that they read on the elected subject matter; otherwise they remain withdrawn from examination.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

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- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, election shall be treated as an election without traverse. Traversal must be presented at the time of election to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.



Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Abstract***

As an aid to future searchers, Applicant is requested to insert the structural formulae of the claimed compounds into the Abstract.

### ***Rejections Under 35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2: The recitation of "analogue" is indefinite and confusing. In chemistry, analogues are compounds in which one or more individual atoms are replaced, either with a different atom, or with a different functional group. Another chemical use of the term refers to a substance which is similar in structure to another substance. Deletion of this term is recommended. In the definition of Y, the phrase "an amino acid residue which may be protected" is indefinite and confusing, because the terms "residue" and "protected" fail to particularly point out and distinctly claim the intended substituent groups. The definition of B as "a carbonyl group" construes compounds with an unsatisfied valence, because a carbonyl group is divalent. In the definition of W and W', the repetition of "a phenyl group" is confusing. It is not possible to determine if this is an inadvertent repetition or has some other intended meaning.

Claim 6: The misspelling of "phenyl" should be corrected. The term "analogue" has been commented on above.

Claims 13 and 14: The term "analogue" has been commented on above.

### ***Rejections Under 35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 USC 102(b) as anticipated by Nagarajan, et al. (Indian J. Chem., Vol. 25B, July 1986, pp. 697-708) (cited by Applicants) describing 4,6,7,8-tetrahydro-5(1H)-cinnolines, Formulae 2a, 2f (page 698), Formulae 7a, 7c and 8 (page 699), Formulae 16 and 18 (page 700), and Formulae 32, 34 and 35 (page 702).

Claim 1 is rejected under 35 USC 102(b) as anticipated by Altomare, et al. (J. Med. Chem., 1998, 41, pp. 3812-3820) (cited by Applicants) describing condensed pyridazines of Formulae 28 and 29 (page 3813, col. 2).

Claim 1 is rejected under 35 USC 102(b) as anticipated by Nagarajan, et al. (J. Med. Chem., 1976, 19, pp. 508-511) (cited by Applicants) describing a 5-oxo-1,4,5,6,7,8-hexahydrocinnoline of compound no. 14, Table I (page 509).

Claims 1 and 13 are rejected under 35 USC 102(b) as anticipated by Petrie, et al., U.S. Pat. No. 6,008,208, issued Dec. 28, 1999 describing FIG. 3A, third compound and FIG. 3B, third compound.

Claim 1 and 13 are rejected under 35 USC 102(b) as anticipated by Orme, et al., US 5919808, patented 19990706, describing RN 190436-31-8, 5(1H)-Cinnolinone, 3-(4-chloro-3-methylphenyl)-4,6,7,8-tetrahydro-7,7-dimethyl- and RN 190436-38-5, 5(1H)-Cinnolinone, 3-(4-bromophenyl)-4,6,7,8-tetrahydro-7,7-dimethyl-, useful for treating

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bone deficit conditions.

### ***Objected Claims***

Claims 1-14 are objected to as directed to both elected and non-elected subject matter. The claims should be amended to be directed to only elected subject matter.

### ***Conclusion***

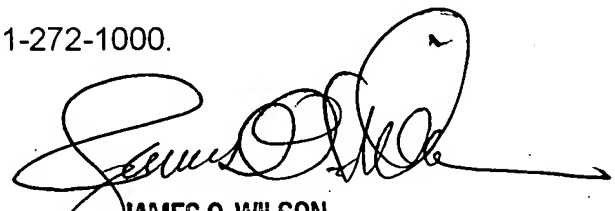
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D., whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday, 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle, J.D.  
9/21/2007



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